Whose Choice Is It Anyway?

Analysis of Comments to and Responses from NIH’s 2017 Refining the HIV Research Enterprise Request for Input on Research Priorities

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Today...

- Background
- Our findings
- Community voices
- Conclusion
- Taking action

- Discussion and Q&A
Background

- The need for multiple HIV prevention options
- Microbicides under threat
- *Refining the HIV Research Enterprise*
  Request for Input on Research Priorities
What we did

- Global sign-on statements
- US Legislators
- Freedom of Information Act (FOIA) request

- Published “Whose Choice Is It Anyway?”

[tinyurl.com/whosechoiceanyway]
What we got

- 330 pages of comments and responses
- “Missing” content

- 120 unique submissions
- Advocates, researchers, academics, elected officials, research networks and industry
- Mostly US and several African countries
- 56 responses from NIAID
What they said

Key Themes – The need for prevention choices
• Choices/options

The family planning field has demonstrated time and time again that providing women with a variety of methods to meet their needs and preferences results in greater product use and satisfaction and fewer unintended pregnancies. This same principle is applicable to the field of HIV prevention.

WOMEN’S HEALTH ADVOCATES (GLOBAL)

We want choices—we are all different and we want different tools so we can choose what suits us best.

YOUNG WOMEN’S GROUP (EAST AND SOUTHERN AFRICA)
What they said

Key Themes – The need for prevention choices

• Continue research on microbicides

Removing the microbicides agenda doesn’t feel like it is in the interest of providing a mix of tools for HIV prevention in young women. *RESEARCHER (SOUTH AFRICA)*

It is foolish to put all our eggs in one basket, or in one category of products. We need long-acting systemic products that don’t require daily administration, just as we need topical on-demand products that don’t require an intense clinical interface and long-term commitment. *LEGISLATORS (US)*
What they said

Key Themes – Product-related comments

• Vaginal microbicides

We love the idea of the ring... We would use it because it’s in and doesn’t bother us for a while… We understand that DAIDS is thinking not to put more research into other forms of rings like this and we don’t think that’s a good idea.

YOUNG WOMEN (EASTERN AND SOUTHERN AFRICA)
The desirability for an on demand, behaviorally-congruent PrEP product has been voiced loudly by the populations at greatest risk of HIV nationally and internationally, especially by young black MSM in the US for more than 10 years... Rectal microbicide products now in clinical development demonstrate the capability to meet these requirements.

RESEARCHER (US)
I am concerned that the focus on systemic HIV prevention modalities compromises the very desirability that Dr. Dieffenbach calls for... For many, systemic products in any shape or form will never be considered desirable—especially in communities with significant medical mistrust... In terms of desirability, microbicides—including rectal and vaginal microbicides—may very well be the most valuable HIV prevention tools currently under study.

RESEARCHER (US)
As African women, we need more research in microbicides which can protect against pregnancy, STI and HIV at the same time.

COMMENTER (AFRICA)
What they said

Key Themes – Product features

• Women-controlled, user-controlled

Microbicides offer a very important opportunity to develop a woman-centered HIV preventive tool... Why kill an idea when you are still looking for an answer?

ADVOCATE (UGANDA)
What they said

Key Themes – Product features

• On-demand, short-term

Systemic products under study (e.g., injectables and implants)… will never meet the needs of people who want—and need—easy-to-use, on-demand tools that readily fit into their lives and do not require systemic application.

RESEARCHER (US)
What they said

Key Themes – Product features
• Non-medicalized methods

We in Africa need a prevention package that can be empowering to the user and less dependent on a very ailing health care system.

COMMENTER (AFRICA)
What they said

Key Themes – Product features

• Behaviorally congruent

Although there have been difficulties in development of topical products, particularly with adherence, there are areas (including enemas) that are behaviorally congruent and hold great promise. We can’t give up on this! *RESEARCHER (US)*
What they said

Key Themes – Specific populations

The black men and transgender men and women of color who are served by [our organization] want more options for HIV prevention.

ADVOCATE (US)

Invest more in microbicides so that more and more adolescent girls and young women are able to find a product that best suits their lifestyles and we can ultimately contribute towards reducing the number of new HIV infections.

COMMENTER (ZIMBABWE)
What they said

Key Themes – Other calls to NIAID

• Don’t combine networks
• GPP/Stakeholder engagement
• Hoping NIAID will listen
• Calls for transparency

We hope our views will be heard and considered because we don’t want our issues to go unnoticed. We would love if—in the future—we were asked first about our needs instead of just coming with the products researchers think will be best and then asking us if we would use them. YOUNG WOMEN (EASTERN AND SOUTHERN AFRICA)
Developing choices for HIV prevention is a smart approach to protecting diverse people and populations. However, choice itself is not the endpoint to which we strive. As stewards of federal investment in HIV research, it is crucial that any prevention tool demonstrate a high degree of safety and efficacy in preventing HIV.

CARL DIEFFENBACH
Key Themes – The prevention needs of women

Developing safe, effective and desirable prevention tools for women has been a longstanding goal for the National Institutes of Health, and is a top priority for the next iteration of the clinical research enterprise.  

CARL DIEFFENBACH

To be clear, NIAID will continue to support development of topical HIV prevention products… That said, we need a focused discussion on what it means to fully protect women from HIV... if it is sufficient to only protect women during vaginal sex, when data indicate that rates of women engaging in vaginal and anal sex are increasing, especially for young women.  

CARL DIEFFENBACH
How NIAID responded

Key Themes – Fiscal constraints and the benefits of one network

Integrating HIV prevention research in one network will ensure that the highest priority research is accomplished, allow for deeper collaborations and partnerships with network experts and other organizations like pharmaceutical companies, which are essential for getting successful products to market.

CARL DIEFFENBACH
How NIAID responded

Key Themes – Support for innovative, meritorious concepts of highly safe and effective tools?

There is no evidence to demonstrate that a rectally applied product that lacks the ability to penetrate system-wide will be able to offer effective protection. However, while systemic protection is critical, systemic delivery is not mandatory. I do acknowledge your position that this position effectively eliminates microbicide research in its current state, but I think this field is in need of a significant evaluation of what is actually desirable, practical, and provides protection equivalent to daily PrEP. The goal should not be to protect a fraction of the population, it should be to develop products that are highly desired, easy to use, and are able to confer safe and effective protection. CARL DIEFFENBACH
Key Themes – No funding for community engagement

While the Be the Generation Bridge Project... complemented site and network-level community engagement activities by laying the groundwork in reaching people in many of these communities, and building research literacy and awareness, funding is no longer possible to support that type of effort.

CARL DIEFFENBACH
Community advocates

Ntando Yola
Irene Hware
Sinazo Peter
Conclusion

• Community AND scientific concerns and priorities largely ignored by NIH
• Contradictory NIH responses—expressing disingenuous “support” for microbicides
• Disappointing submission from HPTN leadership
• Still time to speak up! We are watching you! We want microbicides! We want choices!
Act up.
Fight back!

tinyurl.com/whosechoiceanyway
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#fulltoolbox

#HIVpreventionoptions

#microbicides4all

#usercontrolled

#usercenteredredesign

#ourpreventionchoices

#optionsforpeopleslives
Write to the NIAID/NIH and HPTN leadership to express your views...

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Acknowledgements

• PROJECT DIRECTOR: Jim Pickett
• PROJECT ADVISORS: Danielle Campbell, Manju Chatani-Gada, Anna Forbes, Lauren Glodowski, Ashley Randall +++,
• REPORT AUTHOR: Marc-André LeBlanc
• SPECIAL THANKS: AIDS Foundation of Chicago ($$$) and Lauren Glodowski (FIST!!!)

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Thank you

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